

REMARKS

Claims 1-10 have been rejected under 35 U.S.C. §101 and/or 35 U.S.C. §112, second paragraph, because claim 1 as previously presented recited a use without setting forth any steps involved in the process. Claim 1 has been amended to affirmatively recite method steps, and thus Applicants respectfully submit that these rejections have been overcome.

Claims 11 and 13 have also been rejected under 35 U.S.C. §112, second paragraph, due to an error in antecedence in claim 11. This error has been corrected.

Claims 10 and 12 have been rejected under 35 U.S.C. §102(b) as being anticipated by either Brown (U.S. Patent 5,853,894) or Bepak (WO 99/42154), and claims 11 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brown. Applicants respectfully submit that these rejections have been overcome by the amendments herein. Claim 10, as amended, recites a device for manufacturing a pharmaceutical composition comprising a drug substance and pharmaceutically acceptable excipients in the form of a suspension for inhalation via a pMDI, the device comprising a vessel and components within the vessel configured to mix the drug substance and excipients to form the suspension. An inner surface of the vessel, and regions of the components that contact the drug substance, are coated to reduce adhesion of the drug substance to the inner surface and components relative to the extent to which the drug substance would adhere to the inner surface and components if they were not coated.

Brown does not disclose, for example, components within a vessel that are configured to mix a drug substance and excipients to form a suspension, and in particular does not disclose components having regions that contact a drug substance, which are coated to reduce adhesion of the drug substance to the components relative to the extent to which the drug substance would adhere to the components if they were not coated.

Bepak discloses that certain inner surfaces of an inhaler can be coated to reduce deposition of the inhalable composition on the surfaces. Bepak does not disclose, *inter alia*, a device for manufacturing a pharmaceutical composition comprising a drug substance and pharmaceutically acceptable excipients in the form of a suspension for inhalation via a pMDI,

the device comprising a vessel and components within the vessel configured to mix the drug substance and excipients to form the suspension, as now recited in Applicants' claim 10.

Claims 11 and 13, and Applicants' new claims, are patentable for at least the reason that they depend from a patentable base claim.

In view of the above remarks, Applicants respectfully request that the rejections of record be withdrawn.

It is believed that no fees are due with this submission. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 06275-478US1.

Respectfully submitted,

Date: June 18, 2007

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